

REMARKS

Claims 1-30 are pending in this application. Claims 17, 25 and 26 have been withdrawn from consideration. The claims acted on by the examiner are claims 1-16, 18-24 and 27-30.

Claims 1-16, 18-24 and 27-30 have been provisionally rejected for double patenting over the claims of copending application Serial No. 09/811,542. This rejection is respectfully traversed.

Soft capsules are one piece containers, the manufacture of which comprises filling, forming and sealing of the capsules in a single step. Hard capsules are two-piece containers consisting of a "cap" and a "body." Forming the cap and body is a manufacturing step quite separate from the steps of filling and sealing the unit by fitting the wider bodied cap over the body of the capsule. Those facts were pointed out in the original specification at page 2, line 41, to page 3, line 22.

The physical forms of the two types of capsules are also different. Two documents are submitted herewith:

- ✓ *Die Kapsel* (Symposium "Die Kapsul in Offizin und Industrie", 27, APV-Jahreskongress 1981, Braunschweig); and
- ✓ *Hard Capsules, Development and Technology* (The Pharmaceutical Press, 1987, p. 1).

The documents refer to gelatin capsules, but the principles discussed above also would apply to capsules made from different materials. One of the documents is in German,

but the drawings depicting the different forms should be self-explanatory. Thus, the claimed soft capsules in this application are devices essentially different from the hard capsules claimed in the other case, and are patentably distinct. The fact that the polymer compositions may overlap does not effect the foregoing conclusion. There are also significant differences in the manufacturing processes and the properties of the capsules resulting therefrom. Generally, a polymer suited for the manufacture of one type of capsule is not necessarily suitable for the other type as well.

Claims 1-12, 15, 16, 18, 19, 21 and 27-30 have been rejected under 35 USC § 103 as being unpatentable over GB '457 in view of Harreus. This rejection is respectfully traversed.

The non-relevance of Harreus to soft capsules has been discussed in applicants' previous response. The disclosure of GB '457 does not suitably combine with Harreus in such a way as to establish a case of *prima facie* obviousness against the instant claims.

The properties of the polymers disclosed in GB '457 make them unsuitable for soft capsules. They are soft and sticky, see page 4, lines 81-82. A sticky polymer can not be used in the technically very demanding manufacturing process for soft capsules.

Polymers disclosed on GB '457 also must be water-insoluble. Note that they can be precipitated in water or can be extracted with water for purification. See, for example, working examples 2, 3, 4, 6 and 7. A capsule produced from such polymers would not dissolve sufficiently to be suitable for soft capsules.

Claims 13 and 14 have been rejected under 35 USC § 103 as being unpatentable over GB '457 in view of Harreus and Ishii et al., US 5,965,651 (Ishii). This rejection is respectfully traversed.

The disclosure of Ishii does not remedy the defects in the combination of the two references discussed above. For one thing, the N-vinylcarboxamides of Ishii are chemically completely different from the polymers recited in the instant claims. Furthermore, they are liquid-absorbing materials. That is, they are very different in their behavior from the materials of the claimed invention. Liquid absorbing materials will not dissolve or disperse rapidly in water as do the claimed soft capsules. The Ishii materials remain stable and retain the liquid, water being one of the liquids that can be retained. See col. 2, lines 5-7. The fact that Ishii discloses crosslinking agents with completely different polymers having completely different properties does not complete the requirements for a *prima facie* case of obviousness. See MPEP § 706,02(j).

The combination of references relied on by the examiner epitomizes the type of impermissible hindsight cautioned against in MPEP § 2142, second paragraph. The rejection involves the use of the application of impermissible hindsight, dissection of the references and reassembling the bits and pieces thereof so obtained. It has long been held that such a procedure in formulating a rejection under 35 USC § 103 is completely improper. See, merely for example, *Akzo N.V. v. U.S. International Trade Commission*, 808 F.2d 1471, 1480-81, 1 USPQ2d 1241, 1246 (Fed. Cir. 1986), *cert. denied*, 482 U.S. 909 (1987) and *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 874, 228 USPQ 90, 99

(Fed. Cir. 1985).

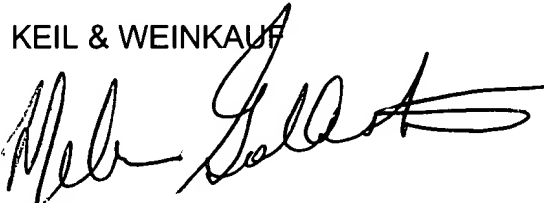
In light of the foregoing comments, it is believed that the examiner's rejections have been obviated, and it is respectfully urged that this application be passed to issue.

A check to cover the one month extension fee of \$110.00 is attached.

Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees to Deposit Account No. 11-0345. Please credit any excess fees to such deposit account.

Respectfully submitted,

KEIL & WEINKAUF

A handwritten signature in black ink, appearing to read 'Mel Goldstein', written over the printed name.

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